

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SEPRACOR, INC.,)	
)	
Plaintiff,)	
)	
v.)	C.A. No. 06-113-KAJ
)	
DEY, L.P. and DEY, INC.,)	
)	
Defendants.)	

ANSWER, COUNTERCLAIMS AND DEMAND FOR JURY TRIAL

Defendants Dey, L.P. and Dey, Inc. (collectively, “Dey”), by their attorneys, respond to Plaintiff Sepracor, Inc.’s (“Sepracor”) Complaint for Patent Infringement (“Complaint”) as follows:

ANSWER

1. Dey is without knowledge or information sufficient to form a belief as to the truth of the allegation of paragraph 1 of the Complaint and therefore denies same.
2. Dey admits the allegations of paragraph 2 of the Complaint.
3. Dey admits the allegations of paragraph 3 of the Complaint.
4. Dey admits that Dey, Inc. is the general partner of Dey, L.P. The remaining allegations of paragraph 4 of the Complaint are legal conclusions not requiring admission or denial.

NATURE OF ACTION

5. Dey admits that the Complaint purports to set forth a patent infringement action under the patent laws of the United States, 35 U.S.C. § 100 *et seq.*, and more particularly 35 U.S.C. §§ 271(e)(2) and 281. Dey admits that Dey, L.P. filed an Abbreviated New Drug Application (“ANDA”) with the U.S. Food and Drug Administration (“FDA”) seeking approval

to engage in the commercial manufacture, use and sale of levalbuterol hydrochloride inhalation solutions prior to the expiration of various United States patents that Sepracor purports to own. Dey denies the remaining allegations of Paragraph 5.

6. The allegations that this Court has subject matter jurisdiction over this action are legal conclusions requiring no admission or denial. The cited statutory provisions speak for themselves.

7. Dey admits the allegations of paragraph 7 of the Complaint.

8. Dey admits the allegations of paragraph 8 of the Complaint.

9. Dey admits the allegations of paragraph 9 of the Complaint.

10. Upon information and belief, Dey admits that U.S. Patent No. 5,362,755 (“the ‘755 Patent”) was issued by the United States Patent and Trademark Office on November 8, 1994 and that a copy of what is purported to be the ‘755 Patent is attached to the Complaint as Exhibit A. Dey specifically denies that the ‘775 Patent was duly and legally issued and is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 10 of the Complaint and, on that basis, denies each and every remaining allegation.

11. Upon information and belief, Dey admits that U.S. Patent No. 5,547,944 (the “‘994 Patent”) was issued by the United States Patent and Trademark Office on August 20, 1996 and that a copy of what is purported to be the ‘994 Patent is attached to the Complaint as Exhibit B. Dey specifically denies that the ‘944 Patent was duly and legally issued and is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 11 of the Complaint and, on that basis, denies each and every remaining allegation.

12. Upon information and belief, Dey admits that U.S. Patent No. 5,760,090 (“the ‘090 Patent”) was issued by the United States Patent and Trademark Office on June 2, 1998 and that a copy of what is purported to be the ‘090 Patent is attached to the Complaint as Exhibit C. Dey specifically denies that the ‘090 Patent was duly and legally issued and is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations

of paragraph 12 of the Complaint and, on that basis, denies each and every remaining allegation.

13. Upon information and belief, Dey admits that U.S. Patent No. 5,844,002 (“the ‘002 Patent”) was issued by the United States Patent and Trademark Office on December 1, 1998 and that a copy of what is purported to be the ‘002 Patent is attached to the Complaint as Exhibit D. Dey specifically denies that the ‘002 Patent was duly and legally issued and is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 13 of the Complaint and, on that basis, denies each and every remaining allegation.

14. Upon information and belief, Dey admits that U.S. Patent No. 6,083,993 (“the ‘993 Patent”) was issued by the United States Patent and Trademark Office on July 4, 2000 and that a copy of what is purported to be the ‘993 Patent is attached to the Complaint as Exhibit E. Dey specifically denies that the ‘993 Patent was duly and legally issued is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 14 of the Complaint and, on that basis, denies each and every remaining allegation.

15. Dey admits that upon information and belief, Sepracor is the current holder of approved New Drug Application (“NDA”) No. 20-837 for XOPENEX® (levalbuterol hydrochloride) Inhalation Solutions.

16. Dey admits that Dey, L.P. has submitted to the FDA an ANDA (No. 77-800), containing “Paragraph IV Certifications,” pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), to the ‘755, ‘994, ‘090, ‘002 and ‘993 Patents, for the purpose of engaging in the commercial manufacture, use and sale of Dey, L.P.’s proposed levalbuterol hydrochloride inhalation solutions before the expiration of such patents. Dey is without sufficient information to form a belief as to the truth of the remaining allegations, including the allegation that the ‘755, ‘994, ‘090, ‘002 and ‘993 Patents cover XOPENEX® (levalbuterol hydrochloride) Inhalation Solutions, or treatment methods using XOPENEX® and therefore denies same.

17. Dey admits that in a letter dated January 9, 2006, Dey, L.P. notified Sepracor that it filed ANDA (No. 77-800) seeking approval to engage in the commercial manufacture, use and sale of Dey, L.P.’s proposed levalbuterol hydrochloride inhalation solutions. Dey admits that

Dey, L.P. also provided Paragraph IV Certifications in the January 9, 2006 letter under 35 U.S.C. § 355(j)(2)(A)(vii)(IV) to the '755, '994, '090, '002 and '993 Patents. To the extent the remaining allegations are inconsistent with Dey, L.P.'s January 9, 2006, letter, Dey denies the remaining allegations in paragraph 17 of the Complaint.

18. Dey admits that in Dey, L.P.'s January 9, 2006 letter, Dey, L.P. stated that it had filed ANDA No. 77-100 and that Dey, L.P. intends to manufacture and sell Dey L.P.'s proposed levalbuterol hydrochloride inhalation solutions before the expiration of the '755, '994, '090, '002 and '993 Patents, each of which was listed in the FDA's Orange Book. To the extent the remaining allegations are inconsistent with Dey, L.P.'s January 9, 2006, letter, Dey denies the remaining allegations in paragraph 18 of the Complaint.

19. Dey admits the allegations of paragraph 19 of the Complaint.

20. Dey admits that in a letter dated January 9, 2006, Dey, L.P. notified Sepracor that all of the claims of the '755 Patent, '994 Patent, '090 Patent, 02 Patent, and '993 Patent are "invalid as anticipated and/or rendered obvious over the prior art," and that further, "at least certain claims will not be infringed, either literally or under the doctrine of equivalents, by Dey's making, using, selling, offering to sell and importing its Proposed Drug Products." Additionally, Dey, L.P. admits that the January 9, 2006 letter provides a "detailed statement of the factual and legal bases for Dey's certification." The letter further states that the Notice Letter is provided without prejudice to Dey's raising other bases and/or defenses as to the validity, infringement and enforceability of this patent in the event of litigation. Dey denies the remaining allegations of paragraph 20.

21. Dey restates and incorporates by reference its responses to the allegations of the foregoing paragraphs 1 through 20 as though fully set forth herein.

22. Dey denies the allegations of paragraph 22.

23. Dey denies the allegations of paragraph 23.

24. Dey denies the allegations of paragraph 24.

25. Dey denies the allegations of paragraph 25.

26. Dey denies the allegations of paragraph 26.

27. Dey is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 27 and therefore denies all such allegations.

28. Dey denies the allegations of paragraph 28.

29. Dey denies the allegations of paragraph 29.

30. Dey denies the allegations of paragraph 30.

RESPONSE TO PRAYER FOR RELIEF

31. Dey denies that Sepracor is entitled to any of the relief that it seeks in its prayer for relief or otherwise.

ADDITIONAL DEFENSES

Without any admission as to the burden of proof or as to any of the allegations in the Complaint, Dey states the following defenses.

First Defense

32. Each purported claim for relief in the Complaint is barred for failure to state a claim upon which relief can be granted.

Second Defense

33. Dey's levalbuterol hydrochloride inhalation solutions that are the subject of ANDA No. 77-800 ("Proposed Levalbuterol Hydrochloride Inhalation Solution Products") do not infringe, and would not infringe, (directly, indirectly, contributorily or by inducement) any valid or enforceable claim of the '755, '994, '090, '002 and '993 Patents.

Third Defense

34. By reason of the prior art and/or statements and representations made to the United States Patent and Trademark Office during the prosecution of the application that led to the issuance of the '755, '994, '090, '002 and '993 Patents, the Patents are so limited that no claim can be construed as covering any Dey activity.

Fourth Defense

35. Each and every asserted claim of the '755, '994, '090, '002 and '993 Patents is invalid for failure to meet one or more of the requirements of Title 35, United States Code, including Sections 101, 102, 103 and 112 and for improper double patenting.

Fifth Defense

36. Sepracor's case is not exceptional under 35 U.S.C. § 285.

Sixth Defense

37. Dey has not willfully infringed the '755, '994, '090, '002 and '993 Patents.

Seventh Defense

38. Dey, Inc. is not properly a party in this action as Sepracor is not entitled to damages and any such claim is premature.

Eighth Defense

39. Dey reserves the right to assert any additional defenses or counterclaims that discovery may reveal.

COUNTERCLAIMS

Defendants and Counterclaim-Plaintiffs, Dey, L.P. and Dey, Inc. bring the following Counterclaims against Plaintiff and Counterclaim-Defendant, Sepracor, Inc. ("Sepracor"), alleges as follows:

JURISDICTION AND VENUE

40. This is an action under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202 and the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, based upon an actual controversy between the parties to declare that Dey is free to continue to seek FDA approval of ANDA No. 77-800, and upon approval by the FDA, to manufacture, use, market, sell, offer to sell, and/or import its Proposed Levalbuterol Hydrochloride Inhalation Solution Products as described in the ANDA.

41. This Court has original jurisdiction over the subject matter of these Counterclaims under 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202.

42. This Court has personal jurisdiction over Sepracor because Sepracor is a Delaware corporation with a registered office in Delaware and/or because Sepracor has designated an agent in Delaware for service of process.

43. Venue is proper in this District under 28 U.S.C. §§ 1391(b) and 1400(b) and by Sepracor's choice of forum.

THE PARTIES

44. Counterclaim-Plaintiff Dey, L.P. is a Delaware limited partnership having a principal place of business at 2751 Napa Valley Corporate Drive, Napa, California. Dey, L.P.'s registered office in Delaware is located at 1209 Orange Street, Wilmington, Delaware, 19801. Dey, L.P.'s registered agent for service of process in Delaware is the Corporation Trust Company, 1209 Orange Street, Wilmington, Delaware, 19801.

45. Counterclaim-Plaintiff Dey, Inc. is a Delaware corporation having a principle place of business at 2751 Napa Valley Corporate Drive, Napa, California. Dey, Inc.'s registered office in Delaware is located at 1209 Orange Street, Wilmington, Delaware, 19801. Dey, Inc.'s registered agent for service of process in Delaware is the Corporation Trust Company, 1209 Orange Street, Wilmington, Delaware, 19801.

46. On information and belief, Counterclaim-Defendant Sepracor is a company organized and existing under the laws of the State of Delaware, with its principal place of business at 84 Waterford Drive, Marlborough, Massachusetts 01752.

PATENTS-IN-SUIT

47. Upon information and belief, United States Patent No. 5,362,755 ("the '755 Patent") was issued by the United States Patent and Trademark Office on November 8, 1994 and is owned by Sepracor.

48. Upon information and belief, United States Patent No. 5,547,994 (“the ‘994 Patent”) was issued by the United States Patent and Trademark Office on August 20, 1996 and is owned by Sepracor.

49. Upon information and belief, United States Patent No. 5,760,090 (“the ‘090 Patent”) was issued by the United States Patent and Trademark Office on June 2, 1998 and is owned by Sepracor.

50. Upon information and belief, United States Patent No. 5,844,002 (“the ‘002 Patent”) was issued by the United States Patent and Trademark Office on December 1, 1998 and is owned by Sepracor.

51. Upon information and belief, United States Patent No. 6,083,993 (“the ‘993 Patent”) was issued by the United States Patent and Trademark Office on July 4, 2000 and is owned by Sepracor.

ACTS GIVING RISE TO THE ACTION

52. Upon information and belief, Sepracor is the current holder of approved New Drug Application (“NDA”) No. 20-837 for XOPENEX® (levalbuterol hydrochloride) inhalation solutions.

53. According to the Food and Drug Administration Center for Drug Evaluation & Research Approved Drug Products with Therapeutic Equivalence Evaluations (“Orange Book”) listings, XOPENEX, or treatment methods using XOPENEX, are claimed in U.S. Patent Nos. ‘755, ‘994, ‘090, ‘002 and ‘993.

54. In a letter dated January 9, 2006, and addressed to Sepracor, Dey, L.P. sent Sepracor written notice that it had submitted to the FDA ANDA No. 77-800 which contained “Paragraph IV Certifications,” pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV). In particular, pursuant to ANDA No. 77-800 and Dey, L.P.’s Paragraph IV Certifications, Dey, L.P. notified Sepracor that it intends to engage in the commercial manufacture, use and sale of Dey, L.P.’s proposed levalbuterol hydrochloride inhalation solution drug products.

55. On or about February 22, 2006, Sepracor filed an action in the District of Delaware against Dey, L.P. and Dey, Inc. for patent infringement of the '755, '994, '090, '002 and '993 Patent under 35 U.S.C. § 100 *et seq.* and more particularly 35 U.S.C. §§ 271(e)(2) and 281. Sepracor alleged that the act of infringement relates to, *inter alia*, Dey, L.P.'s filing of an ANDA for approval to market levalbuterol hydrochloride inhalation solutions.

56. Sepracor further alleged that upon FDA approval of Dey, L.P.'s ANDA No. 77-800, Dey will infringe one or more claims of the '755, '994, '090, '002 and '993 Patents by making, offering to sell, selling and/or importing Dey's levalbuterol inhalation solutions in the United States, and/or by actively inducing and/or contributing to the infringement by others.

57. A declaration of rights between the parties is both appropriate and necessary to establish that Dey has not, does not and will not infringe any valid and/or enforceable claim of the '755, '994, '090, '002 and '993 Patents.

First Counterclaim

Declaratory Judgment of Noninfringement of the '755, '994, '090, '002, and '993 Patents

58. Dey repeats each of the foregoing paragraphs as if fully set forth herein.

59. There is a substantial and continuing controversy between Sepracor and Dey as to Sepracor's assertion of infringement of the '755, '994, '090, '002 and '993 Patents and a declaration of rights between the parties is both appropriate and necessary to establish that Dey does not infringe any claim of the '755, '994, '090, '002 and '993 Patents.

60. The claims of the '755, '994, '090, '002 and '993 Patents have not been infringed by the filing of Dey's ANDA.

61. The manufacture, marketing, use, offer for sale, sale and/or importation of the Proposed Levalbuterol Hydrochloride Inhalation Solution Products would not directly infringe, or induce or contribute to the infringement by others of, the '755, '994, '090, '002 and '993 Patents;

Second Counterclaim

**Declaratory Judgment of Invalidity
of the '755, '994, '090, '002, and '993 Patents**

62. Dey, L.P. repeats each of the foregoing paragraphs as if fully set forth herein.

63. There is a substantial and continuing controversy between Sepracor and Dey as to Sepracor's assertion of infringement of the '755, '994, '090, '002 and '993 Patents.

64. The '755, '994, '090, '002 and '993 Patents are invalid under 35 U.S.C. §§ 101 et seq, including §§ 101, 102, 103 and 112, and/or for improper double patenting.

PRAYER FOR RELIEF

WHEREFORE, Dey respectfully requests that the Court enter judgment as follows:

- A. Dismissing all claims against Dey with prejudice and denying all relief requested by Plaintiff/Counterclaim-Defendant Sepracor;
- B. Declaring that the claims of the '755, '994, '090, '002 and '993 Patents have not been infringed by the filing of Dey, L.P.'s ANDA;
- C. Declaring that the manufacture, marketing, use, offer for sale, sale and/or importation of the Proposed Levalbuterol Hydrochloride Inhalation Solution Products would not directly infringe, or induce or contribute to the infringement by others, any claims of the '755, '994, '090, '002 and '993 Patents;
- D. Declaring that the '755, '994, '090, '002 and '993 Patents are invalid and/or unenforceable;
- E. Awarding Dey its attorney's fees and costs;
- F. Awarding Dey such other and further relief as the Court may deem just and proper.

JURY DEMAND

Dey hereby demands a trial by jury as to all issues so triable.

ASHBY & GEDDES

/s/ John G. Day

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Dated: June 7, 2006
170235.1

CERTIFICATE OF SERVICE

I hereby certify that on the 7th day of June, 2006, the attached **ANSWER, COUNTERCLAIMS AND DEMAND FOR JURY TRIAL** was served upon the below-named counsel of record at the address and in the manner indicated:

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VIA FEDERAL EXPRESS

/s/ John G. Day

John G. Day